

Prepared Testimony of Robert Lanza, M.D. to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, July 12, 2005

Good morning, Mr. Chairman and distinguished members of the committee. My name is Robert Lanza and I am the medical director at Advanced Cell Technology, a stem cell company in the emerging field of regenerative medicine. I am also Adjunct Professor at the Institute of Regenerative Medicine at Wake Forest University School of Medicine.

The field of regenerative medicine is accelerating its pace of progress with many scientific groups worldwide conducting research and preclinical tests of human stem cell lines, and beginning to draw up timetables for clinical development. International teams are beginning to pull away from the researchers in the United States given the current limitations on Federal funding for stem cell research. Access to Federal funding for developing new ways of isolating pluripotent stem cells will not only help address current ethical concerns, but will help the US maintain its leadership position in medical research.

The most basic objection to embryonic stem cell research is rooted in the fact that ES-cell derivation deprives embryos of their potential to develop into complete human beings. To date, there have been no reports in the literature of stem cell lines derived using an approach that does not require destruction of embryos. The President's Bioethics Council chaired by Leon Kass has outlined four approaches for creating stem cells without the destruction of embryos.

The first approach would be to generate stem cells using an embryo biopsy similar to preimplantation genetic diagnosis. "PGD" involves removal of one or two cells called "blastomeres" from an embryo to test for genetic diseases like cystic fibrosis. The procedure is relatively simple and is carried out routinely in IVF clinics worldwide. The ability to generate stem cells using this method could circumvent the ethical concerns voiced by many. Using this approach, we have found biopsied mouse embryos developed to term without a reduction in their developmental capacity. We successfully isolated stem cell lines from single blastomeres, which demonstrated the ability to readily differentiate into derivatives of all three germ layers of the body, passing all the tests generally associated with human ES cells (publication pending).

The Kass report raises two ethical concerns regarding this approach. The first objection is that the biopsy could adversely affect the embryo. We propose a simple solution -- use only blastomeres from embryos undergoing routine PGD. Experts estimate that a thousand healthy infants are born every year from embryos that have undergone PGD - a number sufficient to generate numerous new stem cell lines.

Another objection in the Kass report is that the biopsied cell could have the potential to develop into an embryo. In fact, human blastomeres have never been shown to have the capacity to create viable embryos in the laboratory, and there is an increasing body of scientific evidence suggesting that the cells in morula-stage embryos (8-16 cells) have already committed to becoming either ICM cells or trophectoderm. At a minimum, it is clear that some degree of differentiation has occurred, and there is an increasing consensus that the only "totipotent" cells are the fertilized egg and the first 4-or-so cells produced by its cleavage.

The blastomere approach does not involve the destruction of an embryo, nor could the biopsied cell ever develop into an embryo. Eventually, we hope this method can be used to increase the number of stem cell lines that qualify for Federal funding, and at the same time, avoid the challenges associated with other methods outlined in the Kass report. For instance, an approach favored by many, and first proposed by ACT years ago, uses cloning to sabotage the development of embryos. Supporters claim the “bundle of cells” is not an embryo and could be used to ethically generate stem cells. As a medical scientist, I think it is an abuse of science to use cloning and genetic manipulation to deliberately create crippled human embryos, especially when these manipulations are not carried out for any medical or scientific reason, but rather to address theological problems. Let’s be honest, a human embryo is a human embryo whether or not this or that gene is knocked out. It’s hard to believe that human ensoulment depends on the expression of *cdx2*. The blastomere-approach uses a technique that already exists, and would not require taxpayer funding to further develop human cloning techniques.

The Kass report also proposes two other approaches. One is to derive stem cells from “technically dead” embryos. However, we’re talking about tiny clusters of cells; you can’t take an EEG to determine if there’s loss of brain function. I’ve seen numerous human embryos stop dividing, fooling the embryologist into thinking they’re no longer viable; then, after a significant “resting” period, they go on to generate intact blastocysts. Unfortunately, the only sure way to know if an embryo is dead is if the cells are dead.

The final approach, known as dedifferentiation, doesn’t require human eggs or embryos. This is an exciting concept, and involves taking an adult cell and reprogramming it back into a stem cell in the laboratory. We and several other groups have already generated some exciting data on this, but it’s still preliminary and requires further basic research. This approach holds great promise and there are few, if any ethical concerns.

Given the our research to date and the data generated from animal models, further investigations of the single-cell biopsy and dedifferentiation approaches should be funded and encouraged to determine if stem cells can be derived in humans. We believe that a significant commitment of Federal funding of \$15 to \$20 million would significantly accelerate this research and its likely success within this decade.

We hope the approaches described here today will successfully result in the future expansion of stem cell lines available for human therapies. However, until these approaches are perfected in humans, it is important to emphasize the urgent need for continued access to surplus IVF embryos that would otherwise be discarded. It is for this that I commend the sponsors of Senate Bill 471, and applaud you for your commitment to supporting ES cell research and the advancement of regenerative medicine.

While you were listening to this testimony, another 10 Americans have died of diseases that could potentially be treated using stem cells in the future. It would be tragic not to pursue all the options and methods available to us to get this technology to the bedside as soon as possible.

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